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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/711,585 | 11/13/2000 | Chawnshang Chang | 920920.90045 | 7198 |
| 23859 | 7590 | 05/04/2004 | EXAMINER | |
| NEEDLE & ROSENBERG, P.C. SUITE 1000 999 PEACHTREE STREET ATLANTA, GA 30309-3915 | | | BASI, NIRMAL SINGH | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1646 | |

DATE MAILED: 05/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary**Application No.**

09/711,585

Applicant(s)

CHANG, CHAWNSHANG

Examiner

Nirmal S. Basi

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 10/2/04
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 4-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) 1 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>8/20/04</u> <u>10/2/04</u> <u>12/2/04</u> | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

1. Applicant's election with traverse of Group I (Claims 1) on 10/20/03, is acknowledged. The traversal is on the ground(s) that the inventions of Groups I-VII and IX are sufficiently related and would not overly burden the Examiner. Further Applicant argues TR2, TR4 and RXR all modulate AR and ER and should not be viewed as separate inventions and would not overly burden the Examiner. Applicants arguments have been fully considered but not found persuasive. A search of groups I-VII and IX would not be co-extensive particularly with regard to the literature search. Further, there is no showing that TR2, TR4 and RXR all effect the same nuclear receptor mediated activity and effect the same androgen related disease. An examination of the materially different, patentably distinct inventions in a single application would constitute a serious undue burden on the examiner.

The requirement is still deemed proper and is therefore made FINAL.

Objections

The disclosure is objected to because of the following informalities:

2. Applicants are required to use the heading "Brief Description of the Drawings" to describe the drawings. See MPEP 608.01(f). On page 4, Applicant has written "BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE THE FIGURES"

Further, the Figures must be identified in the Brief Description of the Drawings as Figs. 2A-B, Figs. 3A-B, Figs. 4A-B, Figs. 7A-C, Figs. 8A-C, Figs. 9A-B, Figs. 10A-B and described separately using the letter identifier. Appropriate correction is required.

Claim Rejections - 35 USC § 112, Second Paragraph

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 is indefinite because it is not clear what is an androgen related disease so as to allow the metes and bounds of the claim to be determined. What relationship has to exist for it to be considered an androgen related disease? Further, it is not clear what nuclear receptor mediated transcriptional activity is effected by the test compound and what nuclear receptor mediated transcriptional activity is determined. Also, claim 1 is indefinite because the method steps do not achieve the goal of identifying a compound for use in treatment of androgen related diseases. It is not clear how the final step in the method of "observing the effect of such compound on the level of androgen receptor initiated transcription in the test" relates to achieving the goal of the claim. Further it is not clear, in the absence of controls, how the activity determined can be attributed to the effect of the compound being mediated by the TR4 receptor. The measured activity may be result of the modulation of another protein which is completely unrelated to TR4 orphan receptor. An acceptable method claim must contain three sections: 1) a preamble, 2) method steps that clearly define what is to be done in each step, and 3) a conclusion that what was stated in the preamble was achieved (the

method does not contain specific assay steps and a statement how and when the goal of the claim is achieved).

Claim Rejections - 35 USC § 101 and 35 USC § 112, 1st paragraph

The following is a quotation of 35 U.S.C. 101:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claim 1 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

A "specific utility" is a utility that is specific to the subject matter claimed, as opposed to a "general utility" that would be applicable to the broad class of the invention. A "substantial utility" is a utility that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities. A "well established utility" is a utility that is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material, alone or taken with the knowledge of one

skilled in the art. A "well established utility" must also be specific and substantial as well as credible.

Based on the record, there is not a "well established utility" for the claimed invention. Applicant has asserted utilities for the specifically claimed invention of claim 1. The invention is directed to a method of screening a compound for use in treatment of androgen related diseases comprising testing the compound to determine the effect of the compound on nuclear receptor mediated transcriptional activity mediated by a TR4 orphan receptor.

The specification discloses the TR4 is an orphan receptor. There is no disclosure of the specific compounds that activate TR4 orphan receptor. The physiological ligand for the TR4 orphan receptor is unknown. Chang et al (see IDS, Proc. Natl. Acad. Sci, Vol. 91, pp 6040-6044, 1994) disclose the functions of orphan receptors have been elusive and subject to speculation, page 6040, column 1, second paragraph. Enmark et al (Molecular Endocrinology , IDS C20) disclose, "To date the only well characterized example of an orphan receptor with a connection to a human disease is DAX, see bottom of page 1297 and top of page 1298. There is no disclosure of the specific nuclear receptor mediated transcriptional activity mediated by the TR4 orphan receptor that identifies a compound useful in the treatment of an androgen related disease. No androgen related diseases have been identified that show a specific nuclear receptor mediated transcriptional activity mediated by the TR4 orphan receptor. No compounds have been identified that treat an androgen related disease through specific nuclear receptor mediated transcriptional activity mediated by the TR4

orphan receptor. No compound have been identified by the claimed method that treat any androgen related disease. Further the specific receptor mediated transcriptional activity is not disclosed so it is unclear how to assay for said activity. In light of the specification the skilled artisan can not come to any conclusions as to the function of TR4 orphan receptor and how it related to a specific androgen related disease, or how to use compound that may be identified by claimed method.

The utility of claimed method can not be solely based on the observation that TR4 heterodimerizes with the androgen receptor. In light of the specification and art the skilled artisan can not come to any conclusions as to which compound identified by claimed methods would be useful in treatment of androgen related diseases. TR4 orphan receptor has no disclosed physiological ligand or function. The specification fails to disclose, what disease is associated with androgen/TR4 orphan dysfunction or what drugs affect a specific claimed receptor function. The claimed method may have utility in the future, when the nuclear receptor mediated transcriptional activity mediated by TR4 orphan receptor has been further characterized and its dysfunction or function correlated with a specific androgen related disease state.

A utility to TR4 orphan receptor cannot be assigned without knowledge of what disease is associated with claimed said receptor dysfunction or what drugs/ligands effect a specific TR4 orphan receptor function. Further, even if the undisclosed nuclear receptor mediated activity mediated by the TR4 orphan receptor is affected by a test compound in an assay for screening, the specification does not disclose any specific and substantial interpretation for the result, and none is known in the art. Given this

consideration, the individually claimed method of using claimed method has no “well-established” use. The artisan is required to perform further experimentation on the compound screened itself in order to determine to what “use” any information regarding this compound could be put.

However, in the absence of any disclosed relationship between the compound identified by claimed method, TR4 orphan receptor and an androgen related disease or disorder, any information obtained from said method would only serve as the basis for further research on the observation itself. “Congress intended that no patent be granted on a chemical compound whose sole ‘utility’ consists of its potential role as an object of use-testing.” *Brenner*, 148 USPQ at 696. The disclosure does not present a substantial utility that would support the requirement of 35 U.S.C. §101.

Without knowing a biological significance of the claimed method, one of ordinary skill in the art would not know how to use the claimed invention in its currently available form in a “real world” manner based on the diversity of biological activities possessed by heterpdimeric functions of nuclear receptors. Contrast *Brenner*, 148 USPQ at 694 (despite similarity with adjacent homologue, there was insufficient likelihood that the steroid would have similar tumor-inhibiting characteristics), with *In re Folkers*, 145 USPQ 390, 393 (CCPA 1965) (some uses can be immediately inferred from a recital of certain properties) or *In re Brana*, 34 USPQ 1436, 1441 (Fed. Cir. 1995) (evidence of success in structurally similar compounds is relevant in determining whether one skilled in the art would believe an asserted utility; here, an implicit assertion of a tumor target was sufficiently specific to satisfy the threshold utility requirement).

The assertion that the claimed invention has utility in drug screening, drug development and disease diagnosis, do not meet the standards for a specific, substantial or well-established utility for reasons set forth above. For all the above reasons, the disclosure is insufficient to teach one of skill in the art how to use the invention.

7. Claim 1 is also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. Since neither the specification nor the art of record disclose any activities or properties that would constitute a "real world" context of use for the claimed method further experimentation is necessary to attribute a utility to the method of claim 1.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nirmal S. Basi whose telephone number is 571-272-0868. The examiner can normally be reached on 9:00 AM-5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1646

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Nirmal S. Basi
Art Unit 1646
5/2/04


MICHAEL PAK
PRIMARY EXAMINER